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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/576,636

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Christer Sinderby

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EXAMINER

BLIZZARD, CHRISTOPHER JAMES

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,636	Applicant(s) SINDERBY ET AL.	
	Examiner CHRISTOPHER BLIZZARD	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/26/09, 9/25/07, 10/24/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 11, 12, 23, 24, 27, 30-32, 39 and 40 are rejected under 35

U.S.C. 102(b) as being anticipated by Bennett (2,648,331).

3. Regarding claims 1 and 2, Bennett discloses a method of delivering a combined positive and negative pressure assistance ventilation to a patient comprising; applying a positive pressure to the patient's airway to inflate the patients lungs (column 1, lines 48-51), applying negative pressure around the patient's ribcage or abdomen in order to reduce a load imposed on the patient's lungs (column 1, lines 48-51); and synchronizing simultaneous application of the positive and negative pressure (column 1, lines 48-51).

4. Regarding claim 3, Bennett disclose the method further comprising adjusting the level of positive and negative pressure to avoid application of excessive positive pressure (column 2, lines 23-35).

5. Regarding claim 11, Bennett discloses the method further comprising applying a constant negative pressure around the patient's ribcage or abdomen during inspiration (column 1, lines 18-23).

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6. Regarding claim 12, Bennett discloses the method further comprising synchronizing the triggering and termination of the application of negative pressure with the triggering and termination of positive pressure (column 1, lines 48-51).
7. Regarding claims 23, Bennett discloses a system for delivering a combined positive and negative pressure assistance ventilation to a patient comprising; a positive pressure ventilator (51) connected to the patient's airways for applying positive pressure to the lungs (fig. 1); A negative pressure ventilator installed on the patient's ribcage and abdomen for applying negative pressure (fig. 1); and a controller (52) for controlling the two ventilators (column 5, lines 1-8).
8. Regarding claims 24, 30 and 31, Bennett discloses the controller synchronizing the positive and negative pressure ventilators (column 1, lines 48-51).
9. Regarding claims 27 and 39, Bennett discloses the controller applying a constant negative pressure around the patient's ribcage or abdomen during inspiration (column 1, lines 18-23).
10. Regarding claim 32, Bennett discloses a means for adjusting the level of positive and negative pressure to avoid application of excessive positive pressure (column 2, lines 23-35).
11. Regarding claim 40, Bennett discloses the system with a synchronizing means for the triggering and termination of the application of negative pressure with the triggering and termination of positive pressure (column 1, lines 48-51).

Claim Rejections - 35 USC § 103

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12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 4-10, 13-17, 25, 26, 28, 29, 33-38, and 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bennett (2,648,331) as applied to claims 1, 23 and 30 above, and further in view of Sinderby (5,820,560).

14. Regarding claims 4, 5, and 13, Bennett discloses the claimed method except for detecting a neural inspiratory activation of the patient and applying pressures as a function of the signal. Sinderby teaches a method of detecting a neural inspiratory activation of the patient and applying positive pressure as a function of the signal (column 1, lines 18-24). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the method of Bennett with the step of detecting neural inspiratory activation and to control the ventilation of the patient based on the signal as taught by Sinderby in order to provide the advantage of more precise control of the patient's breathing.

15. Regarding claims 25, 33, and 34, Bennett discloses the claimed system except for a sensor to detect neural inspiratory activation and a controller for that controls the applied pressure level based on the sensor output. Sinderby teaches a system for ventilating a patient with a sensor and controller for detecting a neural inspiratory activation of the patient and applying positive pressure as a function of the signal (column 3, lines 40-45). It would have been obvious to one of ordinary skill in the art at

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the time of the invention to provide the system of Bennett with a sensor detecting neural inspiratory activation and a controller to control the ventilation of the patient based on the signal from the sensor as taught by Sinderby in order to provide the advantage of more precise control of the patient's breathing.

16. Regarding claim 6-10, 26, 28, 35-38, and 41, the combination of Bennett and Sinderby discloses the claimed invention wherein Sinderby teaches using a comparator for comparing the detected neural inspiratory activation with a target level and adjusting the applied pressure level accordingly (column 2, lines 60-67; column 3, lines 1-5).

17. Regarding claims 14-17, 29, and 42-45, the combination of Bennett and Sinderby discloses the claimed invention wherein Sinderby teaches using a comparator for comparing the detected diaphragm movement, analogous abdominal pressure swing, with a target level and adjusting the applied pressure level accordingly (column 2, lines 60-67; column 3, lines 1-5).

18. Claims 18-22 and 46-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bennett (2,648,331) as applied to claims 1, 23 and 30 above, and further in view of Lindley (4,481,938).

19. Regarding claims 18-22 and 46-50, Bennett discloses the claimed invention except for applying a constant negative end expiratory pressure over the abdomen to adjust an end expiratory lung volume. Lindley teaches a device with a method of use for delivering combined positive and negative pressure assistance ventilation to a patient comprising the step of applying a positive end expiratory pressure into the lungs (column 7, lines 1-12), analogous negative end expiratory pressure over the abdomen.

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It would have been obvious to one of ordinary skill in the art at the time of the invention provide the method of Bennett with negative end expiratory pressure over the abdomen as taught by Lindley in order to provide the advantage of treating patient's with respiratory distress syndrome.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Abramov (5,806,512) a system with pressures applied to the lungs and the ribcage, Gattinoni (6,461,315) a system for distributing gas in the lungs of a patient, and McWilliams (5,513,631) a ventilator using a signal other than pressure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BLIZZARD whose telephone number is (571)270-7138. The examiner can normally be reached on Monday thru Friday, 9:00AM -5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)2724835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BLIZZARD/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771